Ethical issues in applying digital solutions for persons with cognitive decline

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RADAR-AD

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Outline

Introduction

- What is a digital biomarker (DBM)?
- Benefits and opportunities of DBMs

Overview of the ethics and governance of DBM research

Examples from RADAR-AD

Discussion

- Lessons learnt from RADAR-AD about the ethics and governance of DBM research
- Recommendations on how to move forward in the field

Introduction

Digital biomarker research, benefits, and opportunities

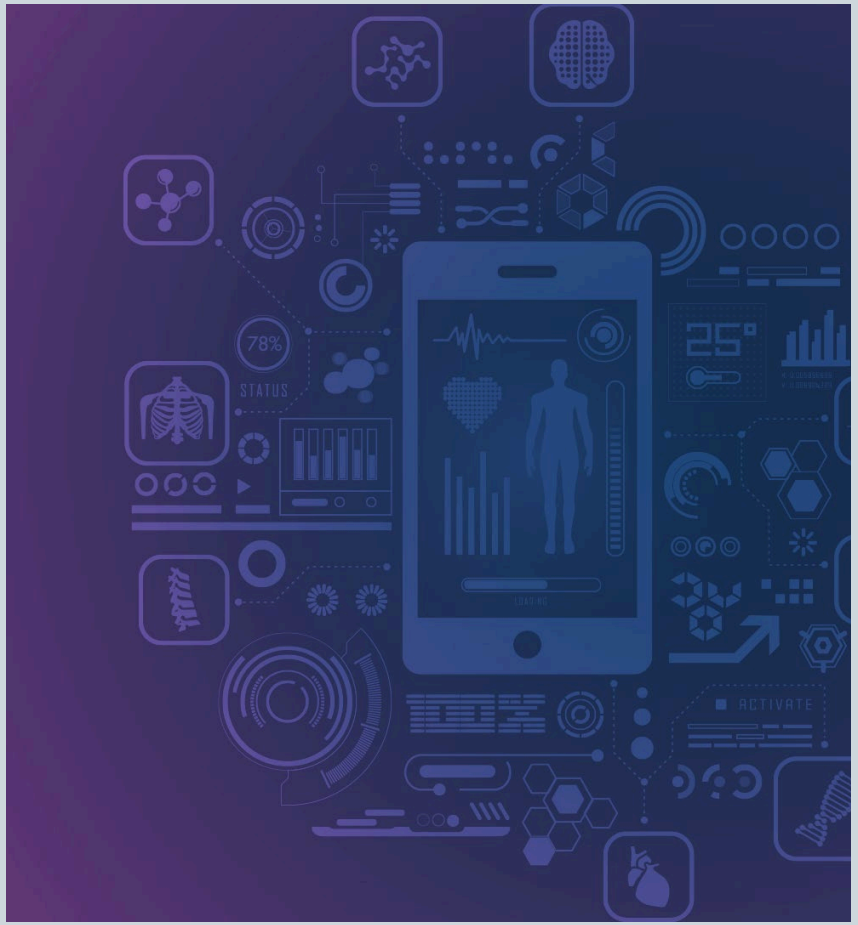
What is a digital biomarker (DBM)?

"An objective, quantifiable measure of physiology and/or behaviour used as an indicator of biological, pathological process or response to an exposure or an intervention that is derived from a digital measure. The clinical meaning is established by a reliable relationship to an existing, validated endpoint."[6]

- European Medicines Agency (EMA)

Benefits and opportunities of DBM

- Frequent and objective assessments
- Real-time insights
- Reduce frequency of in-clinic assessments
- Minimise burden on patients and clinical staff
- Support personalized, accurate diagnoses and treatment.[4,9,13]



Ethical issues in DBM research

Data handling and analysis

- Lack of transparency [4,9]
- Data protection [16-17]
- Data ownership and quality [10]
- The "responsibility towards bystanders" [15]

Informed consent

- Complex concepts, procedures [10]
- Long-term remote monitoring [12]
- Passive data collection and behaviour tracking [14]

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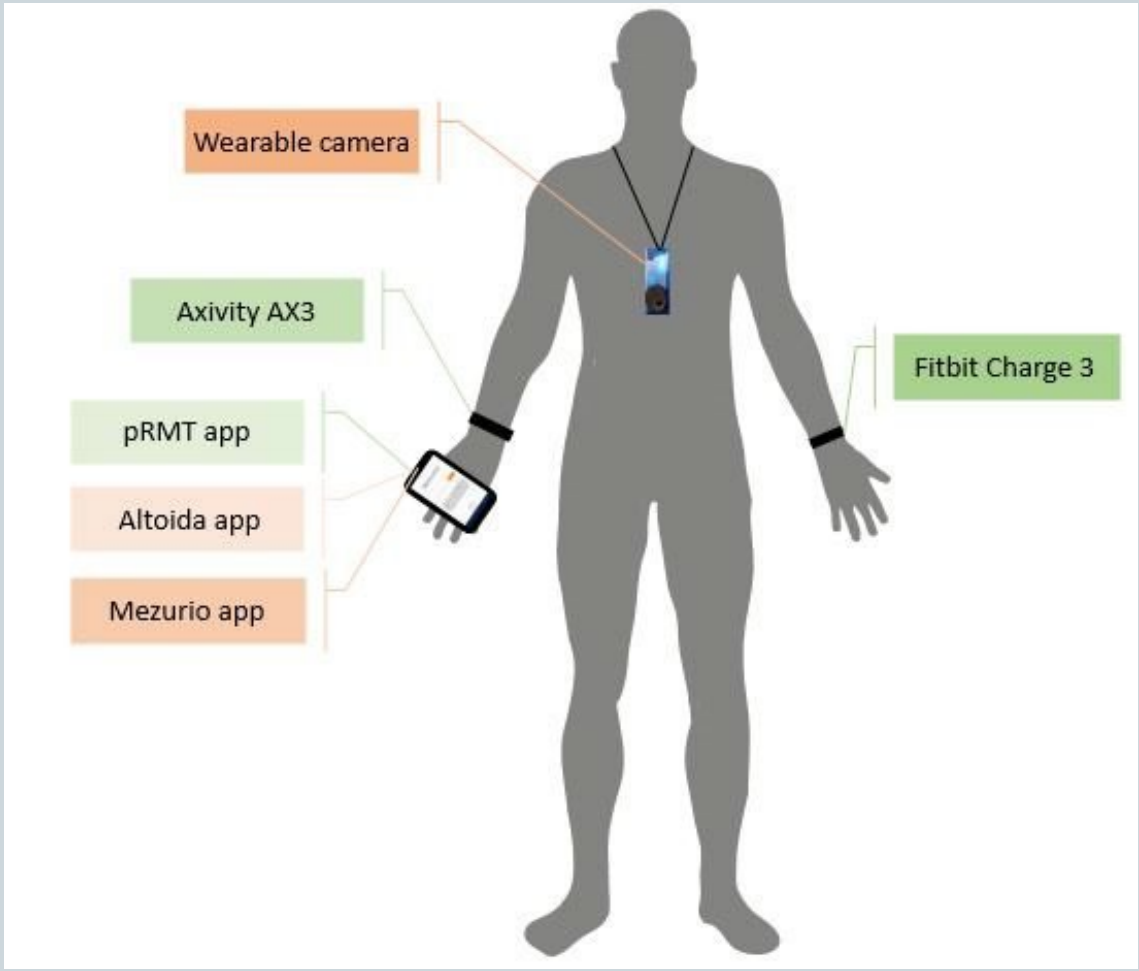
Remote Assessment of Disease And Relapse - Alzheimer’s Disease

RADAR-AD

- Cognitive and functional impairment
- Stages of Alzheimer’s diseases (AD)
- Real-world environment
- 8 weeks
- 229 participants (50 +)
- Digital solutions
- Patient advisory board (PAB) led by Alzheimer Europe



Examples from RADAR-AD

Spanning the entire research process and ecosystem

Ex. 1: Ensuring respect for participants throughout the research process

Challenge 1: informative yet clear informed consent procedures

- Participants' autonomy
- Complexities of digital data collection, analysis and storage [15]

RADAR-AD approach

- Clear and participant-friendly study materials
- Potential concerns
  - Types of messages and information to highlight
  - Additional resources

Ex. 1: Ensuring respect for participants throughout the research process

Challenge 2: involving participants without overburdening them

- Privacy, burden and accessibility
- Long involvement
- Active contribution

RADAR-AD approach

- Minimum burden
- Focus groups
- Unobtrusive technologies
- Public reactions

Ex. 1: Ensuring respect for participants throughout the research process

Challenge 3: ensuring support without being too controlling

- Stewardship and support
- Data integrity and participant adherence
- Respect participants' autonomy and dignity

RADAR-AD approach

- Support strategies for participants
- Three phone calls during remote monitoring
- Questionnaire to prompt discussion

Ex. 2: Sustainability and translation of findings

- Tangible results
- IMI funding requirement
- Incentives to follow through and maximise impact

RADAR-AD approach

- Regulatory process with the EMA [7]
- Follow-up project (PREDICTOM)
- Collaboration for digital endpoints [3]

Ex. 3: Feeding back results to participants, duty of care

- Correct interpretation
- Psychological impact on participants' lives
- Impact of false positive results
- Consequent risk of harm

RADAR-AD approach

- Consumer-grade feedback (e.g. step count, calories)
- Motivation
- Objective and validated measurements

Discussion

Lessons learnt, outstanding questions, and recommendations

Discussion

- Large amounts of data
- Diversify recruitment and inclusivity
- Adapt to context
- Data quality vs quantity
- Representativeness
- Accountability
- Incentives
- Value

Discussion

- Trust and credibility
  - Complex information
  - Sharing of results
  - Transparency
- Clearer guidance
- Accessibility, willingness, and incentives
- Standardising concepts, materials, and processes

Acknowledgements

- Ana Diaz
- Anna-Katharine Brem
- Dag Aarsland
- Dianne Gove
- Federica Lucivero
- Marie-Christine Fritzsche
- Rhoda Au

Thank you to the participants, carers and everyone who contributed to the RADAR-AD study!

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Thank you

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